K112659

Surgical Innovations

MAR - 9 2012

SECTION 5:

510(k) SUMMARY

Submitter: Surgical Innovations plc.
Clayton Wood House
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Leeds
LS16 6QZ
United Kingdom

Tel.: +44 (0)113 230-7597
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Contact Person: Stephen Seed
Quality Manager

Date Summary Prepared: September 2011

Trade Name: Surgical Retractor

Common Name: Surgical Retractor

Classification Name: Laparoscope, General and Plastic Surgery
(21 CFR 876.1500, Product Code GCJ)

Equivalent to: Laparoscopic Retractors (Diamond-Flex) (K092684) Cardinal Health
Nathanson Liver Retractor (K942002) Automated Medical Products
Endo-Retract (K914190) Covidien

Surgical Innovations Limited
Clayton Wood House . 6 Clayton Wood Bank Tel. +44(0)113 2307597 Email. si@surginno.co.uk Reg No. England 2298163
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Surgical Innovations

Device Description: The Surgical Retractor is a Reusable device intended for mobilizing and maneuvering organ and tissue within the cavity during laparoscopic Surgical procedures.

Intended Use: This device is designed as an organ and tissue retractor for the use in minimally invasive surgical procedures to elevate organs and tissues to provide better access as well as visualization and stabilization of surgical sites.

Substantial Equivalence: Laparoscopic Retractors- Cardinal Health, Inc. (K092684)
Nathanson Liver Retractor-Automated Medical Products (K942002)
Endo-Retract- Covidien (K914190)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surgical Innovations
% Ms. Tracey Fearnley
Clayton Wood House
6 Clayton Wood Bank
Leeds LS166QZ
United Kingdom

MAR - 9 2012

Re: K112659
Trade/Device Name: Surgical Retractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 2, 2012
Received: March 5, 2012

Dear Ms. Fearnley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Surgical Innovations

SECTION 4:

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not known

Device Name: Surgical Retractor

Indications for Use: This device is designed as an organ and tissue retractor for the use in minimally invasive surgical procedures to elevate or retract organs and tissues to provide better access as well as visualization and stabilization of surgical sites.

Prescription Use__X__ (Per 21 CFR 801 Subpart D) AND/ OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mxn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112659

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